

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Higuchi et al.

Examiner: Maryam Monshipouri

Serial No.

10/086,913

Group Art Unit: 1652

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March 1, 2002

Customer No.:

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For

PREVENTION AND TREATMENT OF MYCOPLASMA-

ASSOCIATED DISEASES

## SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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November /, 2005

Date of Deposit

Lisa B. Kole

Attorney Name

Registration No.

November

Signature

Date of Signature

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, Applicants respectfully request that the documents listed below and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the listed documents are enclosed.

- 71. Kaji M et al., 2005, "A side effect of neuraminidase inhibitor in a patient with liver cirrhosis," J. Infect. Chemother. 11:41-43.
- 72. Amaya MF et al., 2004, "Structural insights into the catalytic mechanism of Trypanosoma cruzi trans-sialidase," Structure 12:775-784.

- 73. Higuchi ML et al., 2004, "*Trypanosoma cruzi* trans-sialidase as a new therapeutic tool in the treatment of chronic inflammatory diseases: possible action against mycoplasma and chlamydia," Medical Hypothesis <u>63</u>:616-623.
- 74. Higuchi ML et al., 2003, "Coinfection with *Mycoplasma pneumoniae* and *Chlamydia pneumoniae* in ruptured plaques associated with acute myocardial infarction," Arq. Bras. Cardiol. 81(1):12-22.
- 75. Higuchi ML et al., 2003, "Pathophysiology of the heart in Chagas' disease: current status and new developments," Cardiovasc. Res. <u>60</u>: 96-107.
- 76. Watts AG et al., 2003, "*Trypanosoma cruzi* trans-sialidase operates through a covalent sialyl-enzyme intermediate:tyrosine is the catalytic nucleophile," J. Am. Chem. Soc. 9(25): 7532-7533.
- 77. Aiello VD et al., 2002, "A possible role for complement in the pathogenesis of chronic chagastic cardiomyopathy," J. Pathol. <u>197</u>:224-229.
- 78. Buschiazzo et al., 2002, "The crystal structure and mode of action of transsialidase, a key enzyme in *Trypanosoma cruzi* pathogenesis," Molecular Cell <u>10</u>:757-768.
- 79. Dallo SF et al., 2000, "Intracellular DNA replication and long-term survival of pathogenic mycoplasmas," Microb. Pathog <u>29</u>:301-309.
- 80. Palomino AS et al., 2000, "Systematic mapping of hearts from chronic chagasic patients: the association between the occurrence of histopathological lesions and *Trypanosoma cruzi* antigens," Ann. Trop. Med. Parisitol. 94(6):571-579.
- 81. Treanor JJ et al., 2000, "Efficacy and safety of the oral neuraminidase inhibitor oseltamivir in treating acute influenza: a randomized controlled trial. U.S. oral neuraminidase study group," JAMA 283(8):1016-1024.

82. Monto AS et al., 1999, "Efficacy and safety of the neuraminidase inhibitor Zanamivir in the treatment of influenza A and B virus infections." J. Infect. Dis. 180: 254-261.

83. Higuchi ML et al., 1997, "Association of an increase in CD8+ T cells with the presence of *Trypanosoma cruzi* antigens in chronic, human chagasic myocarditis," Am. J. Trop. Med. Hyg. <u>56</u>:485-489.

84. Higuchi ML et al., 1987, "The role of active myocarditis in the development of heart failure in chronic Chagas' disease: a study based on endomyocardial biopsies," Clin. Cardiol. 10:665-670.

85. Libby P et al., 1986, "A neuraminidase from *Trypansosoma cruzi* removes sialic acid from the surface of myocardial and endothelial cells, "J. Clin. Invest. 77:127-135.

86. Sobeslavsky O. et al., 1968, "Adsorption of *Mycoplasma pneumoniae* to neuraminic acid receptors of various cells and possible role in virulence." J. Bacteriol. <u>96(3)</u>:695-705.

Citation of these references is not an admission that any one is prior art against the present invention.

Please charge the fee due for this submission to Deposit Account No. 02-4377. A copy of this paper is enclosed.

Respectfully submitted,

BAKER BOTTS L.L.P.

Lisa B. Kole

PTO Reg. No. 35,225

212-408-2628

Form PTO-1449 U.S. Department of Commerce	Atty. Docket No.	Serial No.	
(REV. 2-82) Patent and Trademark Office	068528.0103	10/086,913	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant: Higuchim, et al.		
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	U.S. PATENT DOCUMENTS						
*Exam. Initial.	No.	Document No.	Date	Name	Class	Subclass	Filing Date if Approximate.

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Exam Initial	No.	Document No.	Date	Country	Class	Subclass	<u>Translation</u> Yes No

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	71	"A Side effect of neuraminidase inhibitor in a patient with liver cirrhosis" by Kaji, et al. <u>J. Infect. Chemother</u> , (2005)(11:41-43)
	72	"Structural Insights into the catalytic mechanism of Trypanosoma cruzi trans-sialidase" by Amaya, et al., Structure, Vol. 12, pp. 775-784, May 2004
	73	"Trypanosoma cruzi trans-sialidase as a new therapeute tool in the treatment of chronic inflammatory diseases: possible action against mycoplasma and chlamydia" by Higuchi, Medical Hypotheses (2004)(63, 616-623).

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Examiner	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	74	"Coinfection with mycoplasma pneumoniae and chlamydia pneumoniae in ruptured plaques associated with acute myocardia infarction" by Higuchi, et al., Arq. Bras Cardiol, Vol. 81, No. 1, 12-22, 2003.
	75	"Pathophysiology of the heart in chagas' disease: current status and new developments" by Higuchi, et al., 2003 European Society of Cardiology, pp. 96-107
	76	"Trypanosoma cruzi trans-sialidase operates through a covalent sialyl-enzyme intermediate: Tryosine is the catalytic nucleophile" by Watts, et al., J. Am. Chem. Soc. 2003, 125, 7532-7533.
	77	A possible role for complement in the pathogenesis of chronic chagasic cardiomyopathy" by Aiello, et al., Journal of Pathology, 2002, 197; 224-229
	78	The Crystal Structure and Mode of Action of Trans-sialidase, a key enzyme in trypanosoma cruzi pathogenesis by Buschiazzo, et al., Molecular Cell, Vol. 10, 757-758, Oct. 2002
	79	Intracellular DNA replication and long term survival of pathogenic mycoplasmas" by Dallo, et al., Microbial Pathogenesis, 2000, 29: 301-309
	80	Systematic mapping of hearts from chronic chagasic patients: the association between the occurrence of histopathological lesions and Trypanosoma cruzi antigens" by Palomino, et al., Annals of Tropical Medicine and Parasitology, Vol. 94, No. 6, 571-579 (2000).
	81	Efficacy and Safety of the Oral Neuraminidase Inhibitor Oseltamivir in Treating Acute Influenza by Treanor, et al., JAMA, Feb. 23, 2000, Vol. 283
	82	Efficacy and Safety of the Neuraminidase Inhibitor Zanamivir in the treatment of Influenza A and B Virus Infections by Monto, et al., Journal of Infectious Diseases, 1999: 180; 254-61.
	83	Association of an increase in CD8+ T cells with the presence of trypanosoma cruzi antigens in chronic human chagasic mycoarditis by Higuchi, et al., Am. J.Trop. Med. Hyg., 56(5), 1997, pp. 485-489

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	84	The role of active myocarditis in the development of heart failure in chronic chagas disease: a study based on endomycardial biopsies by Highuci, et al., Clin. Cardiol. 10, 665-670 (1987)
	85	A Neuraminidase from Trypanosoma cruzi removes sialic acid from the surface of mammalian myocardial and endothelial cells by Libby, et al., J. Clin. Invest., Vol. 77, Jan. 1986, 127-135
	86	Adsorption of Mycoplasma pneumonia to neuraminic acid receptors of various cells and possible role in virulence by Sobeslavsky, et al. Journal of Bacteriology, Sept. 1968, p. 695-705.

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